DEPARTMENT OF HEALTH AND HUMAN SERVICES 52010 Public Health Service

Food and Drug Administration
5100 Paint Branch Pkwy, HFS-607
College Park, Maryland 20740

WARNING LETTER FEB -4 2005

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Merazon Health Products, Inc.
11201 Greenwood Ave. N
Seattle, WA 98133-8612

Dear Sir or Madam:

The Food and Drug Administration (FDA) has reviewed your web site at the Internet address www.meragenesis.com and has concluded that claims in your labeling cause your product "Immune Guard" to be a drug as defined in section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet home page: http://www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201 (g)(1)(B) of the Act]. Your web site claims that your product is useful in the prevention and treatment of influenza.

The Internet labeling of your product bears the following claims:

- "With Immune Guard, you are helping your body's ability to fight many different kinds of influenza viruses and the common cold."
- "A Safe and Natural Alternative to the Traditional Flu shot"

These claims cause your product Immune Guard to be a drug, as defined in section 201(g)(1)(B) of the Act. Because the product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined in section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA). This drug is also misbranded within the meaning of section 502(a) of the Act because its labeling is false and misleading in that it suggests that the drug is effective for the prevention and treatment of influenza, when, in fact, these claims are not supported by competent and reliable scientific evidence. This drug is also misbranded within the meaning of section 502(f)(1) of the Act, in that its labeling fails to bear adequate directions for use.

This letter is not an all-inclusive review of your websites and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please advise this office in writing, within fifteen (15) days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to ensure that similar violations do not occur. If corrective actions cannot be completed within fifteen days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to Compliance Officer Jennifer Thomas at the above address.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition